MINISTRY OF HEALTH

DEPARTMENT OF HEALTH FOR SCOTLAND

CENTRAL HEALTH SERVICES COUNCIL

SCOTTISH HEALTH SERVICES COUNCIL

Classification of Proprietary Preparations

Report of the Standing Joint Committee

LONDON

HER MAJESTY'S STATIONERY OFFICE

1959

SIXPENCE NET

JOINT COMMITTEE ON CLASSIFICATION OF PROPRIETARY PREPARATIONS

Members

The Lord COHEN OF BIRKENHEAD, J.P., M.D., D.Sc., LL.D., F.R.C.P., (*Chairman*)

Professor STANLEY ALSTEAD, M.D., F.R.C.P., F.R.F.P.S.

A. B. DAVIES, Esq., M.B., Ch.B., M.R.C.S., L.R.C.P.

Professor Sir CHARLES DODDS, M.V.O., F.R.S., M.D., D.Sc., F.R.C.P.

H. C. FAULKNER, Esq., M.R.C.S., L.R.C.P.

J. C. HANBURY, Esq., M.A., B.Pharm., F.P.S., F.R.I.C.

Professor C. A. KEELE, M.D., F.R.C.P.

K. S. MAURICE-SMITH, Esq., M.R.C.S., L.R.C.P.

D. MCCALL, Esq., B.Sc., Ph.D., F.L.S.

A. J. PITKEATHLY, Esq., O.B.E., M.B., Ch.B.

D. E. SPARSHOTT, Esq., M.A., M.P.S.

W. G. HONNOR, *Secretary*

Report of the Standing Joint Committee on the Classification of Proprietary Preparations

REVIEW OF CATEGORIES FOR CLASSIFICATION OF PROPRIETARY PREPARATIONS

1. The Standing Joint Committee on the Classification of Proprietary Preparations was appointed in 1954 to continue the work of the Joint Committee on Prescribing which had advised, amongst other recommendations, that proprietary preparations should be classified under six categories, namely,

(1) New drugs of proved value not yet standard.

(2) Proprietary brands of standard drugs, singly or in combination.

(3) Standard preparations, and new remedies of proved valuc, in elegant form or vehicle.

(4) Qualitative and/or quantitative modifications in the composition or combination of standard preparations, or new remedies of proved value, which are not accepted as therapeutically superior to preparations included either alone or in combination in the British Pharmacopoeia, the British Pharmaceutical Codex or the British National Formulary.

(5) Preparations not in the British Pharmacopoeia, British Pharmaceutical Codex or British National Formulary, which in the Committee's view have not been proved of therapeutic value.

(6) Preparations which are a combination of (4) and (5).

2. The Committee have now had a further three years' experience of classifying several thousand preparations. This, and the fact that certain pricing arrangements are now agreed between the Health Departments and the industry, suggest that the time has come for a review and possibly revision of the categories.

3. The major difficulties and misapprehensions which have arisen from the present classification are:

(1) Since we used numbers for the categories there has been a widespread belief, not confined to these isles, that the categories represent a decreasing order of therapeutic merit, i.e. that category 1 indicates the best drugs, and category 6 the worst. This suggests that a number of manufacturers and others have not read or clearly understood the definitions, but we think it desirable to adopt a system of labelling categories which is incapable of such misinterpretation.

(2) We have been asked to categorise some new drugs, not yet standard, for which the claim that they are of proved value is supported by evidence which, though suggestive, is in our view not strong enough. We have then

87131 A 2

asked for additional evidence (especially of controlled clinical trials) and postponed classification until this is forthcoming. If at the earlier stage we had been pressed to classify, we should have had to place the preparation in the "not proved of therapeutic value" category. Neither course is satisfactory since it means that whichever is adopted a doctor may be called upon to justify his prescribing of this drug. We think it advisable to have a category of "suspended judgment" in which new drugs not yet standard but for which there is *prima facie* evidence of value could be placed for a specified period (which would vary with each drug and be determined by the Committee) during which the manufacturer would be asked to provide conclusive evidence of its value. At the end of this specified period (unless the Committee otherwise determine) if the evidence is not presented, the drug will be categorised as "not proved of therapeutic value". But during the period of "suspended judgment" the drug should be prescribable without the prescriber being called upon to justify his prescription. One example will suffice to show the purpose of this. If it is claimed that drug "X" will arrest or cure cancer of the stomach even in a relatively few patients, and the *prima facie* evidence presented with the claim is suggestive, it would clearly be wrong to withhold the drug until its value had been conclusively confirmed or refuted.

(3) Many manufacturers have claimed that their preparation of a standard drug is, from its physical format, mode of standardisation, etc., wrongly described as "not accepted as *therapeutically superior*" to standard preparations, though they do not claim that the therapeutic action is different in type. We have amended the definition to cover what was the intention of category 4, namely, to include *all* preparations of those drugs whose active therapeutic constituents are identical with, or modifications of, those of preparations in the British Pharmacopoeia, British Pharmaceutical Codex or British National Formulary.

(4) Preparations which have an undoubted therapeutic value may be placed in category 6 because in their composition are one or more ingredients which the Committee believe have not been proved of therapeutic value, but are certainly not harmful. In many instances the manufacturers have taken out this or these ingredients and the preparation has then been reclassified. But since in competition in overseas markets certain formulae must be used, and since these may be safely prescribed, it has been suggested that the Health Departments should allow the preparation to be prescribed on E.C. 10 provided that the cost is limited to that of the drugs which are standard preparations or new remedies of proved value not yet standard. The Committee consider that as this suggestion is concerned primarily with cost and not with the therapeutic value of a drug, it is outside their terms of reference.

4. The Committee now advise that the categories should be revised as follows:

Category N. New drugs of proved value which are not yet "standard". (The term "standard" is intended to mean preparations described in the British Pharmacopoeia, British Pharmaceutical Codex and British National Formulary.)

This category replaces the old category 1.)

Category S. { All preparations whose active therapeutic constituents are identical with or modifications of those of "standard" preparations.
Elegant preparations of drugs in category N.
Mixtures of drugs in category N with drugs in category S.
(This category replaces the old categories 2, 3 and 4.)

Category P. Preparations which are not "standard" for which prima facie evidence of therapeutic value is presented, but which the Committee cannot accept as of proved therapeutic value without further evidence, which must be provided within a period stipulated by the Committee.
(This is a new category.)

Category O. Preparations not "standard" which in the Committee's view have not been proved of therapeutic value.
(This category replaces the old category 5.)

Category H. Preparations which are a combination of drugs in category O with those in categories N, S, or P.
(This category replaces the old category 6.)

The letters indicating the categories were chosen as an *aide-mémoire*.

N = New drugs
S = Standard drugs
P = Postponed judgment
O = Not of proved therapeutic value
H = Heterogeneous—Mixture of O with other categories

5. The Committee, which is concerned with prescribing by practitioners in Great Britain who are giving general medical services under the National Health Service Acts of 1946 and 1947, advise:

(1) That preparations in categories N and P be freely prescribable on E.C. 10.

(2) That preparations in category S should be prescribable subject to (i) their not being designated as foods, toilet preparations, or not drugs for National Health Service Purposes by the Definition of Drugs Joint Sub-Committee, (ii) their not being advertised direct to the public, and (iii) agreement on pricing being made between the Health Departments and the manufacturers.

6. Practitioners should be discouraged from prescribing preparations in categories O and H, though we subscribe to the view expressed in the Second Interim Report of the Joint Committee on Prescribing (1950) that "there should be no absolute restriction on the prescribing by a general practitioner of any drug which in his opinion was necessary for the treatment of his patients". The prescribing of drugs in categories O or H however, might lead to the practitioner being called upon to justify his action if the cost of his prescribing is being formally investigated.

COHEN OF BIRKENHEAD (*Chairman*)

W. G. HONNOR (*Secretary*)

(87131) Wt. 3546—9228 K464 1/59 D.L./HE/7

Printed and published by
HER MAJESTY'S STATIONERY OFFICE

To be purchased from
York House, Kingsway, London w.c.2
423 Oxford Street, London w.1
13A Castle Street, Edinburgh 2
109 St. Mary Street, Cardiff
39 King Street, Manchester 2
Tower Lane, Bristol 1
2 Edmund Street, Birmingham 3
80 Chichester Street, Belfast
or through any bookseller

Printed in Great Britain

32–9999